

510(k) Summary of Safety & Efficacy: Argyle Turkel Neonatal/
Pediatric Thoracic Catheter Insertion Tray

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The Argyle Turkel Neonatal/Pediatric Thoracic Catheter Insertion Tray will include all components commonly required to perform a chest drainage procedure in a single procedure-ready package. This procedure tray will be available in several configurations of tray components. This device is a Class II device per 21 CFR 870.1300 or 880.6740, Procode: 74DQR or 80CSS.

The Neonatal/Pediatric Thoracic Catheter is a sterile, single use indwelling catheter, used to create a patent open passageway between the chest cavity and atmosphere or a Chest Drainage Unit (CDU). The catheter is intended to prevent pressure from developing in the chest, averting lung collapse and providing a means for fluid to drain from the chest cavity. The catheter will be available in 8, 10 and 12 fr sizes.

The device incorporates a blunt, multi-sideholed, spring-loaded inner cannula coaxially housed within a conventional sharp-beveled hollow needle. This entire assembly is housed within polyurethane tapered catheter, which is used as a standard small bore percutaneously placed thoracic catheter. The tapered catheter incorporates four distal side-holes to facilitate drainage.

The Argyle Turkel Neonatal/Pediatric Thoracic Catheter Insertion Tray is substantially equivalent to Sherwood Medical's currently marketed Argyle Turkel Safety Pneumothorax Procedure Tray (K934428) in that both share the same basic 1) components, 2) intended use and 3) the catheters are introduced in the chest via a trocar. The major differences are: 1) the proposed device will be indicated specifically for neonatal/pediatric use and 2) the addition of a 10 & 12 Fr catheter for the neonatal/pediatric tray.

The Argyle Turkel Neonatal/Pediatric Thoracic Catheter Insertion Tray is substantially equivalent to Sherwood Medical's currently marketed Argyle Trocar Catheters & Trocar Catheter Kits (preamendment) in that they all: 1) have the same intended use and 2) utilize trocars to introduced the catheters into the chest. The major differences are: 1) the proposed device will be indicated specifically for neonatal/pediatric use and 2) the proposed device is a "safety" device.